DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Number: 95-1267

Howard R. Six, Ph.D.
Connaught Laboratories, Inc.
Route 611
P.O. Box 187
Swiftwater, PA 18370-0187

SEP 27 1996

Dear Dr. Six:

The Supplement to your Product License Application for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) to include the use of Connaught Laboratories, Incorporated's DTaP for the reconstitution of Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) manufactured by Pasteur Merieux Serums et Vaccins, S.A. (PMSV) for immunization of 15-18 month-old children, has been approved.

Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) combined with DTaP by reconstitution is to be administered immediately (within 30 minutes) after reconstitution. Vaccine not used within 30 minutes after reconstitution should be discarded. Any request to extend the time between reconstitution and administration would require the submission of additional physical-chemical and clinical stability data in the form of a Supplement to your PLA.

This information will be included in your Product License Application file.

Any change in the supplier of the licensed Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), or in the manufacturing, testing, packaging or labeling of either product or in the manufacturing facilities will require submission of a Supplement to either your product or establishment license application for our review and written approval prior to implementation. Any such changes which may affect safety, purity and potency of the product when combined with PMSV Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) through reconstitution should also be reported simultaneously to Pasteur Merieux Serums et Vaccins, S.A., the licensed manufacturer of Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate).

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information. In addition, please submit three copies of the introductory advertising and promotional labeling. You may wish to submit the proposed materials in draft form with a form 2567 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike, Rockville, MD 20852-1448. Promotional claims should be consistent with, and not contrary to, approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

It is requested that adverse experiences for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed be submitted in accordance with the adverse experience reporting requirements for licensed biological products pursuant to Title 21 of the Code of Federal Regulations Part 600.80 and that distribution reports be submitted as described in 21 CFR part 600.81. Since your product is characterized as a vaccine, these reports should be submitted to the Vaccine Adverse Event Reporting System (VAERS) using the pre-addressed form VAERS-1.

Sincerely yours,

Wilma M. Egan, for

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

cc: Dr. Jean-Claude Vincent-Falquet